

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/
FENFLURAMINE/DEXFENFLURAMINE)
PRODUCTS LIABILITY LITIGATION) MDL NO. 1203

THIS DOCUMENT RELATES TO:)
SHEILA BROWN, et al.) CIVIL ACTION NO. 99-20593
v.)
AMERICAN HOME PRODUCTS) 2:16 MD 1203
CORPORATION)

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8970

Bartle, J.

November 20, 2012

Claudia K. Dwyer ("Ms. Dwyer" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust").² Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").³

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Dennis P. Dwyer, Ms. Dwyer's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or
(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In August, 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Roger W. Evans, M.D., F.A.C.P., F.A.C.C. Dr. Evans is no stranger to this litigation. According to the Trust, he has signed in excess of 318 Green Forms on behalf of claimants seeking Matrix Benefits. Based on an echocardiogram dated January 8, 1998, Dr. Evans attested in Part II of Ms. Dwyer's Green Form that she suffered from moderate mitral regurgitation and a reduced ejection fraction in the range of 50% to 60%. Based on such findings,

3. (...continued)

contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$556,216.⁴

In the report of claimant's echocardiogram, the reviewing cardiologist, G. Gary Gibbs, M.D., stated that "[t]here is evidence of moderate (2+) mitral regurgitation...."⁵ Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

In January, 2004, the Trust forwarded the claim for review by Kevin S. Wei, M.D., one of its auditing cardiologists.⁶ In audit, Dr. Wei concluded that there was no reasonable medical basis for the attesting physician's finding that claimant had

4. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). Although the Trust does not concede that claimant had a reduced ejection fraction, which is one of the complicating factors needed to qualify for a Level II claim, the Trust does not contest the presence of an abnormal left atrial dimension, which also is one of the complicating factors needed to qualify for a Level II claim. Thus, the only issue is claimant's level of mitral regurgitation.

5. Claimant also submitted an echocardiogram report prepared by Dr. Evans in June, 2002 based on her January 8, 1998 echocardiogram. In this report, Dr. Evans stated that "[t]here is moderate mitral regurgitation. The RJA/LAA ratio is 30%."

6. Following his evaluation of claimant's echocardiogram, Dr. Wei resigned from the program in light of a conflict of interest. Although made available, claimant did not elect to have her claim re-audited.

moderate mitral regurgitation because her echocardiogram demonstrated only mild mitral regurgitation. In support of this conclusion, Dr. Wei explained that the "RJA measures 2.15 and 2.07 cm². LAA measures 20 cm². RJA/LAA ratio <20%."

Based on the auditing cardiologist's finding that claimant had mild mitral regurgitation, the Trust issued a post-audit determination denying Ms. Dwyer's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.⁷ In contest, claimant submitted affidavits from Dr. Evans and Dan A. Francisco, M.D., F.A.C.C. In his affidavit, Dr. Evans confirmed his previous finding that claimant had moderate mitral regurgitation. Dr. Francisco also concluded that claimant had moderate mitral regurgitation and stated that "[t]he echocardiogram tape in question shows 'moderate' mitral valve regurgitation with a RJA/LAA ratio of 29%." Claimant argued, therefore, that she had established a reasonable medical basis for her claim because two Board-Certified cardiologists independently agreed that she had moderate mitral regurgitation. Claimant further asserted that the auditing cardiologist "apparently did not understand the difference between his

7. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Dwyer's claim.

personal opinion ... and the 'reasonable medical basis' standard." (Emphasis in original.)

The Trust then issued a final post-audit determination, again denying Ms. Dwyer's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Dwyer's claim should be paid. On May 20, 2005, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 5246 (May 20, 2005).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on August 23, 2005, and claimant submitted a sur-reply on November 2, 2005. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor⁸ to review claims after the Trust and claimant have had the opportunity to develop the Show Cause

8. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Sandra V. Abramson, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's finding that she had moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Dwyer repeats the arguments she made in contest; namely, that the opinions of Dr. Evans and Dr. Francisco provide a reasonable medical basis for her claim. She also argues that the conclusion of the reviewing cardiologist, Dr. Gibbs, provides a reasonable medical basis for the attesting physician's Green Form Representation. In addition, claimant contends that the concept of inter-reader variability accounts for the difference between the opinions

provided by claimant's physicians and the opinion of the auditing cardiologist, Dr. Wei. According to claimant, there is an "absolute" inter-reader variability of 15% when evaluating mitral regurgitation. Thus, according to Ms. Dwyer, if the Trust's auditing cardiologist or a Technical Advisor concludes that the RJA/LAA ratio for a claimant is 5%, a finding of a 20% RJA/LAA ratio by an attesting physician is medically reasonable.

In response, the Trust argues that the opinion of Dr. Francisco does not establish a reasonable medical basis for the claim because he "merely repeats the findings of Dr. Evans ... without rebutting the findings of the Auditing Cardiologist." The Trust also asserts that the auditing cardiologist's conclusion that there was no reasonable medical basis for the Green Form representation that Ms. Dwyer had moderate mitral regurgitation cannot simply be ascribed to inter-reader variability.

The Technical Advisor, Dr. Abramson, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation. Specifically, Dr. Abramson found that:

In reviewing the transthoracic echocardiogram from 1/08/98, my visual estimate is that there is mild to moderate mitral regurgitation in both the parasternal and apical views. Thus I performed measurements to quantify the mitral regurgitation. I measured the mitral regurgitant jet and the left atrial area in the same frame in four representative cardiac cycles in the apical

views. My measurements for mitral regurgitant jet area/left atrial area are $1.9 \text{ cm}^2/19.7 \text{ cm}^2$, $2.2 \text{ cm}^2/22.9 \text{ cm}^2$, $2.3 \text{ cm}^2/21.0 \text{ cm}^2$, $2.1 \text{ cm}^2/19.0 \text{ cm}^2$. These ratios are 10%, 10%, 11%, and 11%, all of which are considerably less than 20%, which is consistent with mild mitral regurgitation.

There are no measurements on the tape for me to critique.

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. First, claimant does not adequately contest the findings of the auditing cardiologist or the Technical Advisor. She does not rebut the auditing cardiologist's determination that the "RJA measures 2.15 and 2.07 cm^2 . LAA measures 20 cm^2 ," resulting in RJA/LAA ratios of 10.25% and 10.75%.⁹ Nor does she challenge Dr. Abramson's finding that claimant's RJA/LAA ratios were "10%, 10%, 11%, and 11%, all of which are ... consistent with mild mitral regurgitation."¹⁰ Although claimant submitted affidavits from two physicians, neither claimant nor her experts identified any particular errors in the conclusions of the auditing cardiologist and the Technical Advisor. Mere disagreement with the auditing cardiologist or the Technical Advisor without identifying any specific errors by them is insufficient to meet a claimant's burden of proof.

9. For this reason as well, we reject claimant's argument that the auditing cardiologist simply substituted his personal opinion for the diagnosis of the attesting physician.

10. Despite the opportunity to do so, claimant did not submit a response to the Technical Advisor Report. See Audit Rule 34.

Claimant's reliance on inter-reader variability to establish a reasonable medical basis for the attesting physician's representation that Ms. Dwyer had moderate mitral regurgitation also is misplaced. The concept of inter-reader variability is already encompassed in the reasonable medical basis standard applicable to claims under the Settlement Agreement. In this instance, the attesting physician's opinion cannot be medically reasonable where the Technical Advisor concluded that claimant's echocardiogram demonstrates RJA/LAA ratios of at most 11%, and the auditing cardiologist determined that claimant's RJA measurements were 2.15 cm^2 and 2.07 cm^2 with a LAA of 20 cm^2 , resulting in RJA/LAA ratios of less than 20%. Adopting claimant's argument that inter-reader variability expands the range of moderate mitral regurgitation by $\pm 15\%$ would allow a claimant to recover Matrix Benefits with an RJA/LAA ratio as low as 5%. This result would render meaningless this critical provision of the Settlement Agreement.¹¹

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of

11. Moreover, the Technical Advisor specifically took into account the concept of inter-reader variability as reflected in her statement that "it would be impossible for a reasonable echocardiographer to interpret this severity of mitral regurgitation as moderate, even considering inter-reader variability."

Ms. Dwyer's claim for Matrix Benefits and the related derivative
claim submitted by her spouse.